

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 17-19 and 21-35 are pending in the present application. Claim 17 has been amended to recite that the sequence of at least 80% identical to SEQ ID NO: 2 comprises the consensus sequence SEQ ID NO: 7. Moreover, claims 17, 23, 26, 27, 28, 29, 30, 31, 32, 33, 34 and 35 have been amended to insert the word "operatively" in front of the word "bound". Claims 23 and 26-35 have also been amended to recite that the promoter sequence comprises SEQ ID NO: 2 or a sequence at least 80% identical to SEQ ID NO: 2, wherein the sequence at least 80% identical to SEQ ID NO: 2 comprises a consensus sequence SEQ ID NO: 7. Claims 24 and 28-29 have also been further amended to correct the informalities cited by the Official Action. Support for the changes to the claims may be found in the present specification at page 3, lines 20-23 and at page 3, line 32 to page 4, line 2. Claims 1-16, 20 and 36-45 have been cancelled.

In the outstanding Official Action, applicants note that the Information Disclosure Statement (IDS) was objected to for not supplying the dates of two publications cited on Form PTO-1449. At this time, applicants note that the two publications were cited in the International Search Report that was attached with the Information Disclosure Statement. Indeed, the International

Search Report indicates that the BEATTY et al. publication has a publication date of November 17, 1997. The MA QING-HU et al. publication is given a publication date of 1998. For the Examiner's convenience, applicants attach herewith a copy of the Information Disclosure Statement filed with the present application and a revised Form PTO-1449 that reflects the appropriate publication dates of the two articles. In view of the above, applicants respectfully request the consideration of the two publications at this time.

Claims 17, 23 and 26 were objected to for reciting the term "bound". The Examiner suggested inserting the term --operatively-- in front of the word "bound". Indeed, as suggested by the Examiner, applicants have amended claims 17, 23 and 26 in this manner. At this time, applicants would like to thank the Examiner for the suggestion as to how to overcome the objection.

Claim 24 was rejected under 35 USC §112, second paragraph, for allegedly being indefinite. In imposing the rejection, the Official Action stated that the term "the fatty acids" lacked antecedent basis. However, applicants believe that claim 24 has been amended in a manner so as to obviate this rejection.

Claims 17, 18, 19, 21 and 22 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the written

description requirement. Applicants believe the present amendment obviates this rejection.

As noted above, the claims have been amended to recite that the promoter sequence comprises SEQ ID NO: 2 or a sequence at least 80% identical to SEQ ID NO: 2, wherein the sequence at least 80% identical to SEQ ID NO: 2 comprises a consensus sequence SEQ ID NO: 7. As indicated in the present specification (see Example 3, page 15), a highly preserved sequence of 265 base pairs contains all the *cis* information necessary for an expression of specific genes of the region surrounding the embryo. The highly preserved sequence is the consensus SEQ ID NO: 7.

The presence of SEQ ID NO: 7 and the claimed promoter sequence is believed to be sufficient to drive gene expression specifically in the endosperm surrounding region of an embryo and seeds of angiosperms, and at an earlier stage of development of the endosperm. Thus, applicants believe that one of ordinary skill in the art would recognize that applicants were in possession of the claimed invention at the time of filing the application.

Indeed, the Examiner is respectfully reminded that whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19

USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its recitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

Thus, as the claims recite that the structure of the promoter sequence comprises SEQ ID NO: 2 or a sequence at least 80% identical to SEQ ID NO: 2, in which the sequence that is at least 80% identical to SEQ ID NO: 2 comprises a consensus sequence of SEQ ID NO: 7, it is believed that the claims have been amended in a manner to show that the applicants were in

possession of the claimed invention at the time the application was filed.

Claims 17, 18, 19, 21 and 22 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. Applicants believe the present amendment obviates the rejection.

Applicants believe the objection is obviated in view of the amendment of claims 17-22 which recites that the sequence at least 80% identical to SEQ ID NO: 2 comprises the consensus sequence SEQ ID NO: 7.

As noted above, SEQ ID NO: 7 contains all the *cis* information necessary for an expression of specific genes of the region surrounding the embryo, it would be routine for one of ordinary skill in the art to identify the promoter nucleotide sequences comprising SEQ ID NO: 7 and at least 80% identical to SEQ ID NO: 2, which would have the promoter activity as set forth in claim 17. As a result, applicants believe that one of ordinary skill in the art would be able to practice the claimed invention.

Thus, in view of the above, applicants believe that the present disclosure satisfies the enablement requirement.

In the outstanding Official Action, claims 23-24 and 26 were rejected under 35 USC §102(b) as allegedly being anticipated by CZAKO et al. Claims 17-19 and 21-26 were rejected under 35 USC §103(a) as allegedly being unpatentable over CZAKO et al. in

view of GUNN et al. Applicants believe the present amendment obviates this rejection.

Applicants believe that CZAKO et al. fail to anticipate the claimed invention. The expression consensus according to claims 23-24 and 26 now recite a promoter sequence which comprises SEQ ID NO: 2 or a sequence at least 80% identical to SEQ ID NO: 2, wherein the sequence at least 80% identical to SEQ ID NO: 2 comprises the consensus sequence of SEQ ID NO: 7. As CZAKO et al. fail to disclose or suggest this recitation, applicants believe that CZAKO et al. fail to anticipate or render obvious the claimed invention.

In an effort to remedy the deficiencies of CZAKO et al., the Official Action cited to GUNN et al.

However, CZAKO et al. disclose a construct comprising pea vicilin promoter fused to the coding sequence of diphtheria toxin. Promoter of pea vicilin gene is spatially and temporarily restricted.

The article by GUNN et al. relate to isolation of the coding sequence of genes expressed in a restricted region around maize embryo (ESR). However, the pattern of expression shown on Figures 2 and 3 does not result from detection of a single gene but from detection of a set of ESR genes (see BONELLO et al., page 226, beginning at paragraph 4.1).

The expression pattern of these ESR genes is not disclosed by GUNN et al. Thus, one skilled in the art could not

have inferred from GUNN et al. that the promoter of a single of these ESR genes could regulate the expression of a gene operatively bound thereto spatially and temporarily.

Additionally, GUNN et al. do not disclose or suggest a promoter gene sequence. Moreover, they neither teach nor suggest that a consensus sequence of genes specific to the region surrounding the embryo could be sufficient to confer a spatially and temporally restricted expression of genes fused thereto.

Therefore, one skilled in the art would have lacked the teaching that a promoter sequence comprising a sequence at least 80% identical to SEQ ID NO: 2 and comprising the consensus sequence SEQ ID NO: 7 would allow to achieve expression of a gene fused in a spatially and temporarily restricted manner.

Thus, even if one of ordinary skill in the art would combine the teachings of the two publications, one skilled in the art would not have been able to practice the claimed invention in view of the combination of CZAKO et al. and GUNN et al.

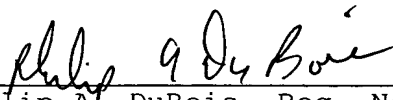
At this time, applicants respectfully request that withdrawn claims 27-35 be examined with claims 17-19 and 21-26. Indeed, claim 27 has been amended to recite a promoter sequence which comprises SEQ ID NO: 2 or a sequence at least 80% identical to SEQ ID NO: 2 comprising the consensus sequence of SEQ ID NO: 7. As a result, applicants respectfully submit that Groups I and II are related by a single inventive concept.

Thus, in view of the above, applicants respectfully request the allowance and passage to issue of the present application, with claims 17-19 and 21-35, as presented.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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Appendix:

The Appendix includes the following items:

- copy of Information Disclosure Statement filed on April 1, 2002
- substitute Form PTO-1449
- article entitled "*Esr* genes show different levels of expression in the same region of maize endosperm"